MEDICAL FEE DISPUTE RESOLUTION FINDINGS AND DECISION

GENERAL INFORMATION

Requestor Name

Memorial Compounding Pharmacy

MFDR Tracking Number

M4-16-2440-01

MFDR Date Received

April 14, 2016

Respondent Name

Federated Service Insurance Company

Carrier's Austin Representative

Box Number 1

REQUESTOR'S POSITION SUMMARY

<u>Requestor's Position Summary</u>: "THIS MEDICATION DOES NOT FALL INTO ANY OF THE CATORGORIES REGARDING PREAUTHORIZATION."

Amount in Dispute: \$609.33

RESPONDENT'S POSITION SUMMARY

Respondent's Position Summary: "The carrier's position as stated on the EOR is that the bill for DOS 06/12/2015 was denied as requiring preauthorization due to the fact that the off-label use of the medications by way of compounding as defined in DWC Rule 134.500(4) constitutes investigational / experimental use as described in Rule 134.500(3)(C) in that the combination of medications prescribed is not supported by scientific or clinical evidence demonstrating the potential efficacy of the treatment, and because broad acceptance of the use of such compound medications is not yet broadly accepted as the prevailing standard of care under Texas Labor Code Sec. 413.014(e)."

Response Submitted by: Parker & Associates, L.L.C.

SUMMARY OF FINDINGS

Dates of Service	Disputed Services	Amount In Dispute	Amount Due
June 12, 2015	Prescription Medication (Compound Cream)	\$609.33	\$609.33

FINDINGS AND DECISION

This medical fee dispute is decided pursuant to Texas Labor Code §413.031 and applicable rules of the Texas Department of Insurance, Division of Workers' Compensation.

Background

- 1. 28 Texas Administrative Code §133.307 sets out the procedures for resolving medical fee disputes.
- 2. 28 Texas Administrative Code §134.500 defines terms used for pharmaceutical benefits.
- 3. 28 Texas Administrative Code §134.503 sets out the fee guidelines for pharmaceutical services.

- 4. 28 Texas Administrative Code §134.530 defines the preauthorization requirements for pharmaceutical services not subject to a certified network.
- 5. The insurance carrier reduced payment for the disputed services with the following claim adjustment codes:
 - 197 Precertification/authorization/notification absent.
 - 930 Pre-authorization required, reimbursement denied.
 - 193 Original payment decision is being maintained. Upon review, it was determined that this claim was processed properly.
 - 351 No additional reimbursement allowed after review of appeal/reconsideration

Issues

- 1. Is the insurance carrier's reason for denial payment supported?
- 2. What is the total reimbursement for the disputed service?
- 3. Is the requestor entitled to reimbursement for the disputed service?

Findings

- 1. The dispute involves a compound medication consisting of Versapro Cream, Ethoxy Diglycol, Amitriptyline HCl, Bupivacaine HCl, Gabapentin USP, Amantadine HCl, and Baclofen. The insurance carrier denied disputed services with claim adjustment reason codes 197 "PERCERTIFICATION/AUTHORIZATION/NOTIFICATION ABSENT," and 930 "PRE-AUTHORIZATION REQUIRED, REMBURSEMENT DENIED."
 - 28 Texas Administrative Code §134.500(3) defines inclusion in the closed formulary as:

 All available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but excludes:
 - (A) drugs identified with a status of "N" in the current edition of the Official Disability Guidlines
 Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and
 any updates;
 - (B) any compound that contains a drug identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates; and
 - (C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care as defined in Labor Code §413.014(a).

28 Texas Administrative Code §134.530(b)(1) provides that preauthorization is only required for drugs that are excluded from the closed formulary. The division finds that Amitriptyline HCl, Gabapentin USP, Amantadine HCl, and Baclofen are included in the closed formulary and have a status of "Y" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary effective on the date of service.

The division finds that because Bupivacaine HCl is an FDA approved drug, it is included in the closed formulary. 28 Texas Administrative Code §134.530(d)(2) states, "Prescription and nonprescription drugs included in the division's closed formulary that exceed or are not addressed by the division's adopted treatment guidelines may be prescribed and dispensed without preauthorization." Per 28 Texas Administrative Codes §§134.500(3) and 134.530(d)(2), although Bupivacaine HCl is not specifically addressed by the ODG/Appendix A, it may be prescribed and dispensed without preauthorization.

The division finds that Versapro Cream and Ethoxy Diglycol are inactive ingredients approved by the FDA. Per 28 Texas Administrative Codes §§134.500(3) and 134.530(d)(2), although these ingredients are not specifically addressed by the ODG/Appendix A, they may be prescribed and dispensed without preauthorization.

Because the disputed compounds consist only of components included in the closed formulary that do not require preauthorization, the insurance carrier's denial reason is not supported. The disputed services will be reviewed in accordance with 28 Texas Administrative Code §134.503.

2. The total reimbursement for the disputed services is established by the AWP formula pursuant to 28 Texas Administrative Code §134.503(c), which states:

The insurance carrier shall reimburse the health care provider or pharmacy processing agent for prescription drugs the lesser of:

- (1) the fee established by the following formulas based on the average wholesale price (AWP) as reported by a nationally recognized pharmaceutical price guide or other publication of pharmaceutical pricing data in effect on the day the prescription drug is dispensed:
 - (A) Generic drugs: ((AWP per unit) x (number of units) x 1.25) + \$4.00 dispensing fee per prescription = reimbursement amount;
 - (B) Brand name drugs: ((AWP per unit) x (number of units) x 1.09) + \$4.00 dispensing fee per prescription = reimbursement amount;
 - (C) When compounding, a single compounding fee of \$15 per prescription shall be added to the calculated total for either paragraph (1)(A) or (B) of this subsection; or
- (2) notwithstanding §133.20(e)(1) of this title (relating to Medical Bill Submission by Health Care Provider), the amount billed to the insurance carrier by the:
 - (A) health care provider...

The requestor is seeking reimbursement for a compound of the brand-name ingredient, Versapro Cream, NDC 38779252903, and generic drugs Ethoxy Diglycol, NDC 38779190301; Amitryiptyline HCl, NDC 38779018904; Bupivacaine HCl, NDC 38779052405; Gabapentin, NDC 38779246109; Amantadine HCl, NDC 38779041105; and Baclofen, NDC 38779038809. The disputed medication was dispensed on June 12, 2015. The reimbursement is calculated as follows:

Date of Service	Prescription Drug	Calculation per §134.503 (c)(1)	§134.503 (c)(2)	Lesser of §134.503 (c)(1) & (2)	Carrier Paid	Balance Due
6/12/15	Compounding Fee	\$15.00	\$15.00	\$15.00	\$0.00	\$15.00
6/12/15	Versapro Cream	(3.200 x 40.8 x 1.09) + 4.00 = \$146.31	\$102.00	\$102.00	\$0.00	\$102.00
6/12/15	Ethoxy Diglycol	(0.342 x 4.2 x 1.25) + 4.00 = \$5.80	\$1.44	\$1.44	\$0.00	\$1.44
6/12/15	Amitriptyline HCl	(18.240 x 1.8 x 1.25) + 4.00 = \$45.04	\$31.63	\$31.63	\$0.00	\$31.63
6/12/14	Bupivacaine HCl	(45.600 x 1.2 x 1.25) + 4.00 = \$72.40	\$48.02	\$48.02	\$0.00	\$48.02
6/12/15	Gabapentin USP	(59.850 x 3.6 x 1.25) + 4.00 = \$273.33	\$188.10	\$188.10	\$0.00	\$188.10
6/12/15	Amantadine HCl	(24.225 x 3.0 x 1.25) + 4.00 = \$94.84	\$38.46	\$38.46	\$0.00	\$38.46
6/12/15	Baclofen	(35.630 x 5.4 x 1.25) + 4.00 = \$244.50	\$184.68	\$184.68	\$0.00	\$184.68

3. The total allowed amount for the disputed service is \$609.33. The insurance carrier paid \$0.00. A reimbursement of \$609.33 is recommended.

Conclusion

For the reasons stated above, the Division finds that the requestor has established that additional reimbursement is due. As a result, the amount ordered is \$609.33.

ORDER

Based upon the documentation submitted by the parties and in accordance with the provisions of Texas Labor Code Sections 413.031 and 413.019 (if applicable), the Division has determined that the requestor is entitled to additional reimbursement for the services in dispute. The Division hereby ORDERS the respondent to remit to the requestor the amount of \$609.33 plus applicable accrued interest per 28 Texas Administrative Code \$134.130, due within 30 days of receipt of this Order.

Authorized Signature

	Laurie Garnes	May 20, 2016	
Signature	Medical Fee Dispute Resolution Officer	Date	

YOUR RIGHT TO APPEAL

Either party to this medical fee dispute has a right to seek review of this decision in accordance with 28 Texas Administrative Code §133.307, 37 *Texas Register* 3833, applicable to disputes filed on or after June 1, 2012.

A party seeking review must submit a **Request to Schedule a Benefit Review Conference to Appeal a Medical Fee Dispute Decision** (form **DWC045M**) in accordance with the instructions on the form. The request must be received by the Division within **twenty** days of your receipt of this decision. The request may be faxed, mailed or personally delivered to the Division using the contact information listed on the form or to the field office handling the claim.

The party seeking review of the MFDR decision shall deliver a copy of the request to all other parties involved in the dispute at the same time the request is filed with the Division. **Please include a copy of the** *Medical Fee* **Dispute Resolution Findings and Decision** together with any other required information specified in 28 Texas Administrative Code §141.1(d).

Si prefiere hablar con una persona en español acerca de ésta correspondencia, favor de llamar a 512-804-4812.